

Attorney's Docket: 2001US405
Serial No.: 10/002,710
Group: 1615

REMARKS

The Office Action mailed June 29, 2006, has been carefully considered. The amendments and remarks presented herein are believed to be fully responsive to the Office Action. The amendments made herein are fully supported by the Application as originally filed. No new matter has been added. Accordingly, reconsideration of the present Application in view of the above amendments and following remarks is respectfully requested.

CLAIM STATUS

Claims 1-9 and 11-19 are pending in this Application. By this Amendment, Applicants have amended the specification to correct an inadvertent typographical error. Specifically, in Example 6 and 7, the compound "caprylyl methicone" is referenced along with the trade name "SilCare 31M50." Applicants have changed the phrase "caprylyl methicone" to the correct chemical designation of "caprylyl trimethicone."

Claim Rejections Under 35 USC § 112. First Paragraph

Claims 1-9 and 11-19 stand rejected under 35 USC § 112, first paragraph. The Office is of the position that the specification "while being enabling for the silsesquioxane having R as a 6-carbon, does not reasonably providing enablement for the full scope of the silsesquioxane where the R is 7-18 carbon, and for all the straight or branched silsesquioxane and where the x is greater than 2." The Office goes on to state "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." Following these, respectfully stated, conclusory statements, the only evidence given by the Office in substantiating the rejection is stated as follows:

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In this case, the full scope of the silsesquioxane given by formula I in the specification represents an invitation to experiment. The specification does not inform the public of the limits of the monopoly asserted.

Courteously stated, it is Applicants position that the Office has not carried its burden of providing a *prima facie* case of non-enablement under § 112, first paragraph.

As stated in the MPEP, § 2164.01, an "analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." (underlining added)... Thus, the enablement requirement of §112, first paragraph has two specific and distinct requirements.

Turning to the first requirement, i.e. how to make the invention, as stated in § 2164.01(b) of the MPEP:

As long as the specification discloses at least one method of making and using the claimed invention that bares a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 USC § 112 is satisfied. (Citations omitted)

With respect to the requirement that the specification teach one with ordinary skill in the art to make the invention throughout the claimed range, Applicants respectfully invite the Office's attention to paragraph 0017 on page 3 through paragraph 0018 on page 4 of the specification. Applicants are of the position that the aforementioned text, *inter alia*, provides more than sufficient guidance to one with ordinary skill in the art how to make the composition as claimed in claim 1, and specifically, to make the invention throughout its entire claimed scope.

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Addressing now the requirement of "how to use the claimed invention," § 2164.01(c) is dispositive as to what satisfies the use requirement of the enablement issue under § 112, first paragraph. Such Section states as follows:

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 USC § 112 is satisfied.

Concerning whether Applicants' specification and claims contain the necessary support for use of the claimed subject matter, the Office's attention is respectfully directed to Paragraph 0021 starting on page 5 through the Examples terminating on Page 35 of the Specification. Applicants are of the courteous position that such detailed disclosure satisfies the mandate of § 112, first paragraph in that it fully teaches one with ordinary skill in the art how to use the claimed invention.

Giving the Office the utmost deference, and most courteously stated, Applicants' are of the position the Office has failed to establish a *prima facie* case of lack of enablement under § 112, first paragraph. Specifically, Applicants rely, *inter alia*, on § 2164.04 of the MPEP wherein it states that the burden to establish a case of non-enablement under § 112, first paragraph, lies with the Examiner. Citing In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971) such Section states, "it is incumbent upon the Patent Office, when ever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions with its own acceptable evidence or reasoning which is inconsistent with the contested statement." (underlining added) The Section requires "the Examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of

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operability with undue experimentation beyond the disclosed embodiments."
(citations omitted).

In supporting its rejection, § 2164.04 insists the Office provide:

[F]actors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence and drawing conclusions based upon these findings of fact.

Respectfully stated, the Office has provided Applicants with no specific finding of facts substantiating the conclusion of a lack of enablement. The Office provides no basis or analysis as to why the Office is of the position that Applicants' have failed to meet the enablement requirement mandated by § 112, first paragraph. With all due respect, on page 3 of the Office Action, the Office provides only the following unsupported conclusion:

In this case, the full scope of the silsesquioxane given by formula I in the specification represents an invitation to experiment. The specification does not inform the public of the limits of the monopoly asserted.


This statement, courteously asserted, does not constitute a basis or an explanation of factors, reasons, or evidence that is required to sustain a *prima facie* case of lack of enablement.

For all the reasons advanced above, it is Applicants' position that a *prima facie* case of §112, first paragraph, lack of enablement has not been made. Applicants are of the position that the specification contains ample support for one with ordinary skill in the art to make and use the invention throughout the complete scope of the claimed subject matter. In consequence, Applicants' respectfully request reconsideration and withdrawal of the rejection.

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In view of the forgoing amendments and remarks, the Application is believed to be in condition for allowance, and reconsideration of it is requested. If the Examiner disagrees, she is requested to contact the attorney for Applicants at the telephone number provided below.

Respectfully submitted,


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